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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,898	03/07/2005	Eiji Tsuru	Q86527	7841
23373 7590 01/02/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER KOSACK, JOSEPH R	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 01/02/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,898	<b>Applicant(s)</b> TSURU ET AL.	
	<b>Examiner</b> Joseph Kosack	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-18 are pending in the instant application.

#### ***Information Disclosure Statement***

The Information Disclosure Statement filed on September 26, 2007 has been considered fully by the Examiner.

#### ***Previous Claim Rejections - 35 USC § 112***

Claims 1-18 were previously rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicant has traversed the rejection on the grounds that the Applicant clearly shows the formation on the alpha form of the crystals, and therefore has enabled one mode of the invention which fulfills the enablement requirement of 35 U.S.C. 112, first paragraph.

The Examiner must respectfully disagree. The entire challenge to the previous 35 U.S.C. 103(a) rejection was that impurities in the prior art would not allow the production of the alpha form, but instead would lead to the beta form of the crystal. The Kitazawa et al. reference does not teach the same process used to generate the crude crystals instantly used in the instant application. See the Tsuru 37 CFR 1.132 declaration of June 6, 2006, executed on June 13, 2006, Figures 1 and 3. The Applicant has not addressed whether the impurities of the Kitazawa et al. process would hinder alpha-form crystal formation such as was shown for Yamagishi et al's process. Another declaration would be necessary to show that the process would actually work to make the alpha form of the crystals. Unless a reproducible method of obtaining the crystals is provided, the crystal is not enabled since after the expiration of the patent,

one of skill in the art would be unable to get the proper crude crystals in order to recrystallize without undue experimentation. Therefore, based on the evidence at hand, the rejections of claims 1-18 must be currently maintained until definitive evidence is provided to rebut the prima facie case of lack of enablement.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

***The Nature of the Invention***

The nature of the invention is the alpha form of the compound currently known as KMD-3213 is claimed, along with medicaments and a method of using the crystal.

*The State of the Prior Art and the Predictability or Lack Thereof in the Art*

The prior art teaches the compound and similar methods of crystallization. For example, Yamagishi et al. (JP07-330726A) teach the dissolving of crude crystals in heated ethyl acetate, and allowing the solution to stand at room temperature. See Reference Example 30, page 24, paragraph 184.

The lack of predictability of the art has been established by the two declarations under 37 CFR 1.132 executed by Eiji Tsuru on June 13, 2006 and December 27, 2006 to show that that process, even with minor modifications known in the art, would produce the beta form of the crystal and not the alpha form. The basis for showing that the prior art process does not produce the alpha form is that a different process of making the compound was used in the instant application, which was **not** disclosed originally and was disclosed in the declaration. There is no evidence as to when, if ever, the process was publicly disclosed before, therefore it must be currently assumed that this is the first disclosure of the instant process.

*The Amount of Direction or Guidance Present and the Presence or Absence of Working*

*Examples*

The written description states that the alpha form can be made by dissolving crude crystals in heated ethyl acetate and allowed to stand at room temperature. The description does not state how the crude crystals were obtained. The Examiner originally interpreted this to mean that any crude crystal can be used to perform this

process and made rejections under 35 U.S.C. 103(a) in the actions of February 6, 2006, and July 27, 2006.

*The Breadth of the Claims*

The breadth of the claims is the alpha form of the compound currently known as KMD-3213 is claimed, along with medicaments and a method of using the crystal.

*The Quantity of Experimentation Needed*

The quantity of experimentation needed is undue experimentation. One of skill in the would have had to come up with the process for making the compound that was kept secret, in order to generate the proper crude crystals referred to in the Examples in the specification.

*The Level of Skill in the Art*

The level of skill in the art of organic synthesis and pharmaceuticals is high. However, due to the unpredictability in the art as described above, one of ordinary skill would be unable to make or use the claimed compound without undue experimentation in order to practice the invention as claimed.

Thus, the specification fails to provide sufficient support of the preparation and use of the alpha form of the compound currently known as KMD-3213. As a result, the application would require one of skill to perform an exhaustive search and an inordinate number of experiments in order to make or use the claimed polymorph.

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to

engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

***Conclusion***

Claims 1-18 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

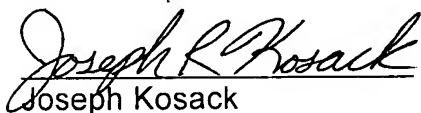
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 6:30 A.M. until 4:00 P.M. The examiner has every other Friday off.

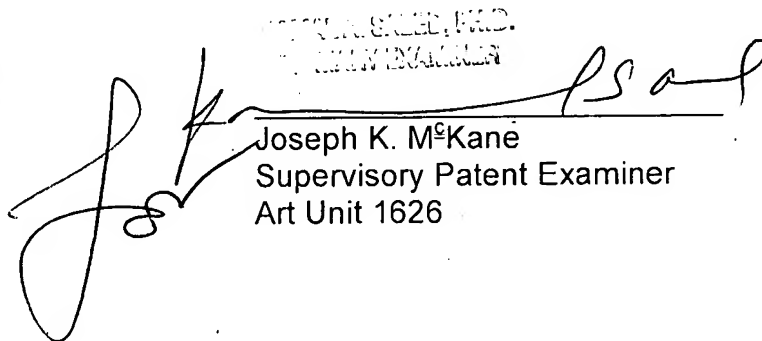
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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